



## **REGIONAL CENTER FOR DIAGNOSTIC, PROGNOSTIC AND PREDICTIVE BIOMARKERS (CRIBT) Azienda ULSS 12 VENEZIANA**

### **PRESENTATION**

#### **SHORT CHRONOLOGICAL SUMMARY**

The CRIBT was founded in 1977 as a Laboratory in the Division of Radiotherapy at the Regional Hospital in Venice. In 1987 the CRIBT was recognized by the Veneto Region as the Regional Center for the Study of Biological Markers of Malignancy (CRIBT). In 1997 it was identified as one of the reference laboratories for the "Receptor and Biomarker Study Group" (presently known as PathoBioGroup), of the European Organization for the Research and Treatment of Cancer (EORTC). In 2001 it was integrated into the Department of Clinical Pathology of the Azienda ULSS 12 Veneziana. In 2005 it was affiliated with the Consorzio Istituto Oncologico Veneto IRCCS. In 2009 it was confirmed by the Veneto Region as a Regional Specialized Center with characteristics of excellence with its new denomination being Regional Center for Diagnostic, Prognostic and Predictive Biomarkers. This new qualification of the Center focuses its primary research activities in the oncology field but also conducts research projects on neurodegenerative, cardiovascular and immune system pathologies.

#### **CRIBT AND RESEARCH**

The mission of the CRIBT is translational research, whose more relevant characteristics are multidisciplinary and focus on clinical application.

Over the past few years research projects have been managed according to a Project Management Approach, that covers the definition of objectives, work planning, coordination of activities, monitoring of work in progress applying corrective measurements when requested and management of final results (i.e. publications or patents)

Between 2006-2010, CRIBT has conducted 47 research projects thanks to the diversity of collaborations and funding (Finalized institutional funds : 9; general purpose institutional funds: 15; donations or collaboration with private firms: 23).

#### **ACTIVITIES**

The activities of CRIBT focus principally on translational research concerning biomarkers in oncology, neurodegenerative diseases, cardiovascular and immune system pathologies. In addition, CRIBT has developed expertise and skills in the following areas:

#### **AREAS OF EXPERTISE**

1. Validation of new biomarkers for clinical use:
  - a. study clinical value of diagnostic, prognostic and predictive biomarkers;
  - b. development of decisional criteria for the determination of biomarkers in serial blood sampling to optimize their clinical use in diagnosis and therapy monitoring.



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2. Health Technology Transfer (HTA)
  3. Organization and management of biobanks or archives of biological material and definition of pre-analytical procedures.
  4. Systematical appropriateness monitoring through the outcome analysis as well as demographic and epidemiological research.
  5. Production, dissemination or adaptation of guidelines
  6. Continuous education, training and tutoring of researchers and collaborating proficiencies (i.e., research nurses)
  7. Promotion and/or diffusion of scientific information.

#### **AREAS OF RESEARCH AND ON GOING DEVELOPMENTS**

CRIBT pursues a strategic research project oriented towards the identification of novel biomarkers in serum or in innovative biological matrices. The principal investigation are as follows:

1. Relationship between biomarker of inflammation or immune response and development, progression or response to treatment in various diseases (cancer, neurodegenerative diseases, cardiovascular diseases);
2. Research on vectors and physiological concentrations of biomarkers (red blood cells, exosomes).

#### **EXPERTISE**

CRIBT can offer the following areas of expertise and skills to scientific, technological or industrial partners:

#### **ANALYTICAL SKILLS**

##### Traditional immunoassay (1 assay – 1 biomarker)

1. Determination of any commercially available biomarker according to certified standards (GLP, ISO 2008).
2. Validation and optimization of commercially available assay methods.
3. Development of assay methods for new biomarkers.
4. Optimization and validation of commercially available assay methods in matrices other than those already patented (i.e. tissue extracts, culture fluids, biological fluids).

##### Multiplexing assay ( 1 assay – many biomarkers)

1. Determination of any commercially available biomarker panel according to certified standards (GLP, ISO 2008).
2. Customization of assay methods for the determination of novel biomarkers.
3. Customization of assay methods for the use in matrices other than those already patented (i.e. tissue extracts, culture fluids, biological fluids) with special expertise in the determination of inflammatory signaling molecules involved in angiogenesis.

##### Ligand Binding Assay

1. Quantitative determination of steroid receptors in tissue extracts (quantitative analysis with evaluation of affinity constant).
2. Development of new assay methods for the determination of diverse receptors or ligands.



### **PRE-ANALYTICAL SKILLS**

1. Preparation of blood derivatives (i.e. plasma, serum, platelet enriched plasma, buffy-coat) according to Standard Operating Procedures (SOPs).
2. Preparation of different tissue fractions.
3. Development of SOPs for both the determination and biobanking of different matrices.
4. Development of SOPs for "fragile" biomarkers.
5. Organization and management of sample management in multi-center research projects.
6. Professional training (i.e for research nurses) and site-visits on the pre-analytical phases.

### **TRANSVERSAL SKILLS**

1. Systematic review of the literature oriented to:
  - a. explore unmet needs of translational research on biomarkers;
  - b. evaluate reliability for clinical application (either in routine or in clinical trials) of available technologies for biomarker determination.
2. Organization and management of banking of biological material.
3. Organization of project management and specific training on professional study design, project budgeting, systematic use of management tools and professional monitoring of work in progress in relation to the adherence to the study aims, established timetable and available resources.

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